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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,877	08/02/2001	Jerry Y. Jonn	104226.01	4857

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EXAMINER

CHOI, FRANK I

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 01/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/919,877

Applicant(s)

JONN ET AL.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 18-58 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 59-68 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-68 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17,59-68, drawn to compositions.
- II. Claims 18-27,46-58, drawn to methods of treating tissue.
- III. Claims 28-45, drawn to kits.

The inventions are distinct, each from the other because of the following reasons:

Inventions I or III, and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the process of using the product as claimed can be practiced with another materially different product in that different tissues adhesives are known and used in the art and as evidenced by the different method claims and the product as claimed can be used to bond substrates other than tissues.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination consists of kit claims which does not require that the

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components be combined in a composition. The subcombination has separate utility such as adhesives for bonding substrates other than tissues.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Groups I and III in that Groups I and III do not require a search of the method of use and the search required for Group III is not required for Groups I and II in that Groups I and II do not require the search of kits. As such, it appears that prosecution of all three inventions would constitute an undue burden on examiner and restriction for examination purposes as indicated is proper.

Examiner additionally required an election of species in which Applicant elected butyl lactoyl cyanoacrylate as the first monomer, octyl alpha-cyanoacrylate as the second monomer and benzalkonium halides as the polymerization inhibitor. However, Examiner hereby withdraws the election of species of requirement.

During a telephone conversation with Joel Armstrong on 1/8/2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-17, 59-68 and the species above. Affirmation of this election must be made by applicant in replying to this Office action except for the election of species which requirement has been withdrawn by examiner. Claims 18-58 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

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application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1,5,6,8-11,14,17,68 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Akimova et al. (US 4,981,483) or EP 0 374 252.

Akimova et al. expressly discloses compositions and films comprising ethyl-alpha-cyanacrylate, ethoxyethyl-alpha-cyanacrylate, polyacrylic acid, polyvinyl alcohol and glycerol falling within the scope of applicant's claims (Columns 5-10).

EP 0 374 252 expressly disclose compositions and films comprising ethyl-alpha-cyanacrylate, ethoxyethyl-alpha-cyanacrylate, monoalkyl ester of polyethylene glycol, dimethyl ketone, citric acid and tannic acid falling within the scope of applicant's claims (Pgs. 8-16).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same

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exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978).

Claims 1-4,8-17,59-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Clark et al.* (US Pat. 5,981,621) in view of *Kronenthal et al.* (US Pat. 3,995,641), *Collins et al.* (Abstract), EP 0 965 623 and *Harwood et al.* (US Pat. 5,344,902).

Clark et al. teach a composition comprising at least one monomer, such as alkyl ester cyanoacrylates and alkyl alpha cyanoacrylates, at least one plasticizer and a mixture of anionic and radical stabilizers, such as sulfur dioxide, hydroquinone, p-methoxyphenol and butylated hydroxyanisole (Column 2, lines 63-68, Columns 3-6). It is taught that in applying composition a polymerization initiator, such as benzalkonium chloride, is used and may be readily selected by one of ordinary skill in the art without undue experimentation (Column 11, lines 18-68)

Kronenthal et al. teaches carbalkoxyalkyl 2- cyanoacrylates which are readily assimilated by tissues and exhibit a relatively low degree of inflammatory tissue response (column 1, lines 60-68, Column 2, lines 1-11).

Collins et al. teach the longer chained alkyl cyanoacrylates, such as octyl 2- cyanocrylate are more effective tissue adhesives and hemostasis-inducing agents than the lower homologues. It is further taught that an adhesive combining low toxicity, the rapidly polymerizing characteristics of the higher homologues with the biodegradability of the methyl monomer would be highly desirable.

EP 0 965 623 teach the combination of sulfuric acid and sulfur dioxide with free radical stabilizers and 2-octyl cyanoacrylate compositions which exhibit greater stability as compared to compositions of the prior art (Pg. 13, lines 1-42).

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The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or film having a first monomer and a different second monomer where the absorption rate of the first monomer species is different from the absorption rate of the second monomer species. However, the prior art amply suggests the same as it is known in the art to combine different monomers in forming medical adhesives. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to combine an alkyl ester cyanoacrylate with an octyl 2-cyanoacrylate with the expectation that absorption of the composition could be adjusted readily by modifying the ratio of the two monomers and the composition would have low toxicity. Further, one of ordinary skill in the art would have been motivated to combine sulfur dioxide and sulfuric acid with radical stabilizers such as hydroquinone, p-methoxyphenol and butylated hydroxyanisole with the expectation that the composition would be more stable.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Claims 1,5-11,14,17,68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al. (US Pat. 5,981,621) in view of Banitt (US Pat. 3,559,652), Collins et al. (Abstract), EP 0 965 623 and Harwood et al. (US Pat. 5,344,902).

Clark et al. teach a composition comprising at least one monomer, such as alkyl ether cyanoacrylates and alkyl alpha cyanoacrylates, at least one plasticizer and a mixture of anionic and radical stabilizers, such as sulfur dioxide, hydroquinone, p-methoxyphenol and butylated hydroxyanisole (Column 2, lines 63-68, Columns 3-6). It is taught that in applying composition

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a polymerization initiator, such as benzalkonium chloride, is used and may be readily selected by one of ordinary skill in the art without undue experimentation (Column 11, lines 18-68)

Banitt teaches that alkoxyalkyl 2-cyanoacrylates are biodegradeable and have minimal toxicity (Column 1, lines 70-75, Column 2).

Collins et al. teach the longer chained alkyl cyanoacrylates, such as octyl 2- cyanocrylate are more effective tissue adhesives and hemostasis-inducing agents then the lower homologues. It is further taught that an adhesive combining low toxicity, the rapidly polymerizing characteristics of the higher homologues with the biodegradability of the methyl monomer would be highly desirable.

EP 0 965 623 teach the combination of sulfuric acid and sulfur dioxide with free radical stabilizers and 2-octyl cyanoacrylate compositions which exhibit greater stability as compared to compositions of the prior art (Pg. 13, lines 1-42).

The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition or film having a first monomer and a different second monomer where the absorption rate of the first monomer species is different from the absorption rate of the second monomer species. However, the prior art amply suggests the same as it is known in the art to combine different monomers in forming medical adhesives. Further, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to combine an alkyl ether cyanoacrylate with an octyl 2-cyanoacrylate with the expectation that absorption of the composition could be adjusted readily by modifying the ratio of the two monomers and the composition would have low toxicity. Further, one of ordinary skill in the art would have been motivated to combine sulfur dioxide and sulfuric acid with radical stabilizers

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such as hydroquinone, p-methoxyphenol and butylated hydroxyanisole with the expectation that the composition would be more stable.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Conclusion


A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

January 10, 2003



JOHN PAK
PRIMARY EXAMINER
GROUP 1600

